ode: 4150-36

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0279]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-0279-60D and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, or call (202) 795-7714 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Department of Health and Human Services (HHS) Registration of an Institutional Review Board (IRB) Form

Type of Collection: Extension

OMB No. 0990-0279

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting a three-year extension of the Department of Health and Human Services (HHS) Registration of an Institutional Review Board (IRB) Form, OMB No. 0990-0279. The purpose of the IRB Registration Form is to provide a simplified procedure for institutions engaged in research conducted or supported by HHS to satisfy the (1) HHS regulations for the protection of human subjects at 45 CFR 46.103(b), 45 CFR 46.107, and 45 CFR 46, subpart E, Registration of Institutional Review Boards; and, the Food and Drug Administration (FDA) regulations for institutional review boards at 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

Annualized Burden Hour Table

IRB Registration Form	Number of Respondents	Number of Responses per Respondents	Average Burden per Response	Total Burden Hours
Update and Renew Registration	5,800	2	0.5	5,800
Initial and Update Registration	400	2	1/0.5	600
Total				6,400

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.

[FR Doc. 2022-03239 Filed: 2/15/2022 8:45 am; Publication Date: 2/16/2022]